UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP., **Plaintiff,** v. **SANDOZ INC.,** **Defendant.**	C.A. No. 3:20-cv-00783-BRM-DEA [redacted]

DEFENDANT SANDOZ INC.'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO DISMISS COUNTS 1 AND 2 OF PLAINTIFF'S COMPLAINT

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I. INTRODUCTION

In this Hatch-Waxman case, Plaintiff Merck Sharpe & Dohme Corp.'s ("Merck") is asserting one patent, U.S. Patent No. 8,263,600 ("'600 patent"), against Sandoz Inc. ("Sandoz"). The '600 patent expires in less than two years on April 1, 2022 [redacted] For this reason, Merck's Complaint fails to state a claim and there is no case or controversy between the parties. Merck's Complaint should be dismissed in its entirety.

Merck's Complaint contains two counts of infringement: Count 1 alleges infringement of the '600 patent under 35 U.S.C. § 271(e)(2) [redacted] and Count 2 alleges future infringement of the '600 patent under the Declaratory Judgment Act and 35 U.S.C. §§ 271(a)-(c).

Count 1 should be dismissed because the Hatch-Waxman Act makes clear that an Abbreviated New Drug Application ("ANDA") must seek FDA approval ***before*** the applicable Orange Book patents expire to establish a claim under § 271(e)(2). [redacted] As a result, Merck also no longer has jurisdiction to maintain its current complaint and dismissal is also appropriate under Fed. R. Civ. P. 12(b)(1). Nonetheless, Merck has refused to dismiss Sandoz from this case

because [redacted]

Count 2 should be dismissed because Merck's speculative claims for future infringement are far too uncertain to support declaratory judgment jurisdiction. Merck's alleged controversy is predicated on Sandoz obtaining FDA approval and marketing its ANDA product before the expiration of the '600 patent, [redacted]

II. BACKGROUND

A. Current Litigation

The current litigation concerns Sandoz's ANDA No. 202481 for posaconazole oral suspension. The '600 patent is the sole patent-in-suit and Sandoz is the sole defendant in this litigation.

The events giving rise to this suit began in December 2019 when Sandoz notified Merck that its ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") stating that the '600 patent is invalid, unenforceable, and/or will not be infringed by the proposed ANDA product. (Dkt. 1, ¶¶ 25-26.)

Sandoz's notice letter included an Offer of Confidential Access ("OCA") to its ANDA, which, if accepted, would allow Sandoz to share portions of its ANDA [redacted] its notice letter. (*See* Dkt. 8.) Merck did not

immediately accept the OCA. Instead, on January 23, 2020, Merck filed suit alleging infringement of the '600 patent. (Dkt. 1.) For the next four months, the parties continued to negotiate the terms of the OCA and finalized terms on May 15, 2020. (Ex. Q, May 15 Email Abraham to Hansen.) Sandoz produced its ANDA three days later on May 18, 2020. (Ex. R, May 18 Email from Abraham.)

In June, the parties reached an impasse as to whether Sandoz's ANDA provides enough information for Plaintiff [redacted] (Ex. S, June 18 Email Collins to Abraham.) [redacted] Plaintiff nonetheless demanded further documentation, which, if it even exists, would be difficult to locate and obtain given that [redacted] Moreover, during negotiations, it was unclear that Plaintiff would even be satisfied with the additional documentation requested. (Ex. S.)

B. [redacted]

The '600 patent expires in less than two years on April 1, 2022. (Ex. B, OB Listing.) The current litigation is in the early pleadings stages and, as shown on the FDA's website, Sandoz has not received any FDA approval – tentative or otherwise – for its ANDA. (Ex. C, New Drug Approvals.) [redacted]

[redacted]

[redacted] The '600 patent is not eligible for a 30-month stay because it is a "pop-up patent" that did not issue until 2012, which is after Sandoz's ANDA No. 202481 was submitted to the FDA. 21 U.S.C. § 355(j)(5)(B)(iii) (stating that 30-month stays are available for patents "for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) before the date on which the application (excluding amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted . . . ."); Ex. H at 8-9 ("[T]he MMA precludes 30-month stays for later listed patents, that is, those patents submitted to FDA on or after the data the ANDA or 505(b)(2) application submitted."). Thus, Plaintiff seeks to obtain via stipulation a bar on Sandoz challenging the '600 patent that is not otherwise available for the '600 patent.

C. [redacted]

In 2011, Merck's wholly-owned subsidiary sued Sandoz alleging that the same ANDA at issue in this case infringed other, now-expired patents that were previously listed in the Orange Book in connection with Noxafil® suspension. *Schering Corp. v. Sandoz, Inc.*, No. 3:11-cv-02589, Dkt. 1 (D.N.J. May 4, 2011). [redacted]

[1] Schering originally asserted infringement of three patents in the prior case, U.S. Patent Nos. 5,661,151, 5,703,079, and 6,958,337 ("'337 patent"). No. 3:11-cv-2589, Dkt. 1. Schering later filed an amended complaint dropping its assertion that Sandoz infringes the '337 patent. *Id.*, Dkt. 32. Sandoz likewise dropped its declaratory judgment counterclaims for the '337 patent. *Id.*, Dkt. 33.

[redacted] The patents in the earlier suit have since expired. (Ex. A, SNDZ-POSA0000170.) Sandoz did not file [redacted] with respect to those patents.

III. LEGAL STANDARDS

Under Rule 12(b)(6), a complaint that "fail[s] to state a claim upon which relief can be granted" must be dismissed. Fed. R. Civ. P. 12(b)(6). The moving party bears the burden of showing that the complaint fails to state a claim. *Gould Elecs., Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000). In reviewing a motion filed under Fed. R. Civ. P. 12(b)(6), the Court must assume that all factual allegations in the complaint are true. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Legal conclusions "must be supported by factual allegations" and "are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009).

In evaluating a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a court may consider the pleadings, exhibits attached to the pleadings, matters of public record, and any documents "integral to or explicitly relied upon" in the pleadings. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997); *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) ("A court may consider an undisputedly authentic document that a defendant attached as an exhibit to a motion to dismiss if the plaintiff's claims are based on the document.").

Under Rule 12(b)(1), a case may be dismissed for lack of subject-matter jurisdiction. Fed. R. Civ. P. 12(b)(1). "Challenges to jurisdiction under Rule 12(b)(1) may be either facial or

factual." *AstraZeneca AB v. Anchen Pharms., Inc.*, No. 11-2317 (JAP), 2014 U.S. Dist. Lexis 79201, at *9 (D.N.J. June 11, 2014) (internal citation omitted). A facial attack challenges the sufficiency of the pleadings, but a court reviewing a factual challenge "may consider evidence outside the pleadings." *Gould Electronics Inc.*, 220 F.3d at 176. "The party invoking federal jurisdiction bears the burden of establishing [the] elements" required for jurisdiction. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). "When considering a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), a court attaches 'no presumptive truthfulness' to the allegations of the non-moving party, and 'the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims.'" *Abraxis Bioscience, Inc. v. Navinta LLC*, No. 07-1251 (JAP), 2008 U.S. Dist. Lexis 63598, at *6 (D.N.J. July 31, 2008). At all times, the plaintiff has the burden of proof that jurisdiction does in fact exist. *Mortensen v. First Fed. Savings & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977).

IV. ARGUMENT

A. Count 1 of Merck's Complaint Should be Dismissed For Failure to State a Claim Upon Which Relief Can be Granted

[redacted]

[redacted] Section 271(e)(2)(A) provides in relevant part:

> It shall be an act of infringement to submit . . . an [ANDA] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . ***if the purpose of such submission is to obtain approval*** . . . to engage in the commercial manufacture, use, or sale of a drug, . . . claimed in a patent or the use of which is claimed in a patent ***before the expiration of such patent***.

35 U.S.C. § 271(e)(2) (emphasis added). Count 1 of Merck's Complaint, which alleges infringement of the '600 patent under 35 U.S.C. § 271(e)(2), [redacted]

As such, Merck cannot maintain its claim that Sandoz infringes the '600 patent under 35 U.S.C. § 271(e)(2) and Count 1 of Merck's Complaint should be dismissed without prejudice. [redacted] In *Lundbeck*, Sandoz converted it Paragraph IV certifications to Paragraph III certifications. [redacted] the *Lundbeck* Plaintiffs (represented by the same lead counsel as the present case) refused to dismiss Sandoz absent a stipulation that Sandoz would never submit a Paragraph IV certification [redacted] The *Lundbeck* court dismissed Plaintiffs' claims for infringement of the PIII-ed patents for failure to state a claim because "[i]t is now clear from the pleadings that Sandoz no longer seeks FDA approval of its ANDA product '***before the expiration of the patent***.'" *Id.* at *10 (emphasis added). [redacted]

1. Merck Fails to State a Claim For Infringement of The '600 Patent Under 35 U.S.C. § 271(e)(2)(A) [redacted]

Merck's count alleging Sandoz's ANDA infringes the '600 patent under 35 U.S.C. § 271(e)(2) should be dismissed [redacted][2] As Sandoz

[2] Indeed, Merck's Complaint expressly points to Sandoz's Paragraph IV certification as the basis for Merck's claims: "Sandoz has infringed the '600 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 202481 ***with a Paragraph IV certification*** and seeking FDA approval of ANDA No. 202481 prior to the expiration of the '600 Patent." (Dkt. 1, ¶ 34) (emphasis added).

explained to Merck, [redacted]

The remedies available under § 271(e)(4) confirm that § 271(e)(2) is limited to applications seeking ANDA approval ***before*** the expiration of the applicable patents. *See generally Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 412 (2012) ("consider[ing] statutory text and context together" to construe statute). For example, §§ 271(e)(4)(A)-(C) define the "only remedies which may be granted by a court for an act of infringement" based on an ANDA submission as follows:

> (A) the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is ***not earlier than the date of the expiration of the patent which has been infringed***,
>
> (B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . ,
>
> (C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug . . . .

35 U.S.C. § 271(e)(4) (emphasis added). As emphasized above, "the remedy for a prevailing plaintiff [in a Hatch-Waxman case] is an injunction delaying approval of a defendant's ANDA

until expiration of all listed Orange Book patents."[3] *AstraZeneca AB*, 2014 U.S. Dist. Lexis 79201, at *16 (emphasis added). As such, § 271(e)(4) makes clear that § 271(e)(2) is limited to applications seeking ANDA approval ***before*** the expiration of the applicable patents [redacted] *See Lundbeck*, 2020 U.S. Dist. Lexis 113213, at *11 (granting dismissal because "Sandoz, by converting from Paragraph IV to Paragraph III, has already essentially given Plaintiffs what they asked for from the Court.").

Supreme Court precedent confirms the need for a Paragraph IV certification for suit under § 271(e)(2). In *Eli Lilly & Co. v. Medtronic, Inc.*, the Supreme Court observed that § 271(e)(2) "define[s] a new (and somewhat artificial) act of infringement for a very limited and technical purpose that relates only to certain drug applications." 496 U.S. 661, 676 (1990). The Supreme Court specifically noted:

> [The Hatch-Waxman] scheme will not work, of course, if the holder of the patent pertaining to the pioneer drug is disabled from establishing in court that there has been an act of infringement. . . . Thus, an act of infringement had to be created for these ANDA and paper NDA proceedings. That is what is achieved by § 271(e)(2) -- the creation of a highly artificial act of infringement that consists of submitting an ANDA or a paper NDA containing the ***fourth type of certification*** that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.

Id. at 678 (emphasis added). Thus, the Supreme Court "ha[s] read § 271(e)(2) to require an ANDA with a Paragraph IV certification against a listed patent." *Eisai Co. v. Mut. Pharm. Co.*, 2007 U.S. Dist. Lexis 93585, at *35 (D.N.J. Dec. 20, 2007).

Federal Circuit precedent further reinforces the necessity of a Paragraph IV certification for a claim for infringement under section 271(e)(2). *See, e.g.*, *AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1374 (Fed. Cir. 2012) ("The [Hatch-Waxman] Act specifies that

[3] Section 271(e)(4)(C) likewise does not apply because it allows for damages or other monetary relief "only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug" before patent expiration.

filing an ANDA containing a Paragraph IV certification constitutes an act of infringement."); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) ("The ANDA provisions now codified at 35 U.S.C. § 271(e)(2)(A) also created an artificial act of infringement that consists of submitting an ANDA containing a [Paragraph IV] certification . . . ."); *Bristol-Myers Squibb Co.*, 69 F.3d at 1131 ("Inclusion of a paragraph IV certification in an ANDA, however, is deemed an act of infringement."); *see also Eisai*, 2007 U.S. Dist. Lexis 93585, at *42 ("[T]his Court holds that to establish an act of infringement pursuant to § 271(e)(2), the ANDA must contain a Paragraph IV certification against a patent listed in the Orange Book for the drug in question.").

[redacted] *E.g.*, *Takeda Pharm. Co. v. Aurobindo Pharma Ltd.*, No. 3:15-cv-07635, Dkt. 82 (D.N.J. May 24, 2018) (Ex. I); *Tris Pharma, Inc. v. Actavis Laboratories FL, Inc.*, No. 1:14-cv-01309, Dkt. 83 (D. Del. Oct. 29, 2015) (Ex. J); *UCB Inc. v. Hetero USA Inc.*, No. 1:13-cv-01213, Dkt. 29 (D. Del. Oct. 1, 2015) (Ex. K); *Pfizer Inc. v. Zydus Pharm. USA, Inc.*, No. 1:12-cv-00808, Dkt. 32 (D. Del. Nov. 16, 2012) (Ex. L); *Pfizer Inc. v. Zydus Pharm. USA Inc*., No. 1:12-cv-00808, Dkt. 132 (D. Del. June 19, 2013) (Ex. M); *Purdue Pharma LP v. Par Pharm., Inc.*, No. 1:17-cv-01334-RGA, Dkt. 8 (D. Del. Oct. 12, 2017) (Ex. N); *In re: '318 Patent Infringement Litigation*, No. 1:05-cv-00356-KAJ, Dkt. 186 (D. Del. May 5, 2006) (Ex. O). Indeed, in 2012, [redacted] Further, unless brought at the eve of trial, opposition to such dismissals is typically unsuccessful. *E.g.*, *AstraZeneca AB*, 2014 U.S. Dist. Lexis. 79201, at *18. Here, the case was only just filed in January 2020, and is in the early pleadings stage. Sandoz has not yet answered the Complaint and no case deadlines have even been set.

2. [redacted]

In the meet-and-confer process, Merck stated that it will not agree to dismiss Sandoz, [redacted] Sandoz is not required to make such a stipulation in order to eliminate a claim under 35 U.S.C. § 271(e)(2). The Hatch-Waxman Act establishes a cause of action only where an ANDA includes a Paragraph IV certification stating that the ANDA submitter seeks the final FDA approval necessary to commercially make, use, and sell the product ***before*** patent expiration. *See* 35 U.S.C. § 271(e)(2).

[redacted]. "A claim is not ripe for adjudication if it rests on contingent future events that may not occur as anticipated, or indeed may not occur at all." *AstraZeneca*, 669 F.3d at 1380-81 (quoting *Texas v. United States*, 523 U.S. 296, 300 (1998)). As a result, a § 271(e)(2) infringement analysis is limited to "whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Id.* at 1365; *see also AstraZeneca*, 669 F.3d at 1381 ("Regardless what may or may not occur in the future, the infringement analysis under § 271(e)(2) is limited to whether the accused infringer's ANDA seeks approval for activities that would constitute infringement of the asserted patents."). [redacted]

[redacted] Accordingly, dismissal of Count 1 of Merck's Complaint is appropriate.

3. Plaintiffs Cannot Distinguish *Lundbeck*

As noted previously, the District of Delaware's recent dismissal in *Lundbeck* of counts alleging infringement under 35 U.S.C. § 271(e)(2) [redacted] (Ex. G.) In correspondence between the parties, Plaintiff attempted to distinguish *Lundbeck* by pointing to Count 2, which alleges infringement of the '600 patent under the Declaratory Judgment Act rather than under 35 U.S.C. § 271(e)(2). (Dkt. 1, ¶¶ 44-53.) However, Count 2 does not allege any facts that might give rise to declaratory judgment jurisdiction separate and apart from a § 271(e)(2) claim. Such duplicative counts for infringement under the Declaratory Judgment Act are improper and should be dismissed [redacted] Plaintiff cannot bootstrap a §271(e)(2) count to an improper Declaratory Judgment count and somehow make both viable.

B. Count 1 of Merck's Complaint Should be Dismissed For Lack of Subject Matter Jurisdiction Under Fed. R. Civ. P. 12(b)(1)

[redacted] also gives rise to a host of jurisdictional defects in Merck's claim for infringement under section 271(e)(2) (Count 1), which requires dismissal for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1).[4]

[4] [redacted] should be for failure to state a claim under Fed. R. Civ. P. 12(b)(6) or lack of jurisdiction under Fed. R. Civ. P. 12(b)(1), and at least one district court has granted dismissal on the latter basis. *E.g.*, *AstraZeneca AB*, 2014 U.S. Dist. Lexis 79201, at *16. Whether the Court dismisses here pursuant to 12(b)(6) or 12(b)(1), the same analysis applies. *AstraZeneca*, 669 F.3d at 1381; *see also Susquehanna Valley Alliance v. Three Mile Island Nuclear Reactor*, 619 F.2d 231, 239 (3d Cir. 1980) ("Returning that Count

1. The Court Lacks Subject Matter Jurisdiction Because Merck Cannot State a Claim For Infringement Under 35 U.S.C. § 271(e)(2)

The Court lacks subject matter jurisdiction over Count 1 because 35 U.S.C. § 271(e)(2) provides the jurisdictional basis for Merck's claims for infringement in these counts, and Merck cannot state a cognizable claim for infringement under 35 U.S.C. § 271(e)(2) for the reasons stated in Section IV.A. *See AstraZeneca AB*, 2014 U.S. Dist. Lexis 79201, at *17-18.[5] [redacted]

2. [redacted]

It is well established that "standing is an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan*, 504 U.S. at 560. The "irreducible constitutional minimum of standing" requires demonstration of three elements: (1) an injury in fact; (2) a causal connection between the injury and the conduct complained of; and (3) a likelihood that the injury will be "redressed by a favorable decision." *Id.* As the party invoking federal jurisdiction, Merck bears the burden of establishing each element. *Id.*

a. [redacted]

Merck's first insurmountable obstacle to Article III standing for Count 1 is the injury in fact requirement. The Supreme Court has defined an injury in fact as "an invasion of a legally

[redacted]

[5] In *AstraZeneca Pharmaceuticals L.P. v. Apotex Corp.*, the Federal Circuit held that counts alleging infringement of method patents for which the ANDA filers had submitted section viii statements should have been dismissed for failure to state a claim under Fed. R. Civ. P. 12(b)(6), rather than lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). 669 F.3d at 1381.

protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not 'conjectural' or 'hypothetical.'" *Lujan*, 504 U.S. at 560.

Merck's alleged injuries flow from Sandoz's submission of an ANDA seeking FDA approval of Sandoz's ANDA product ***before*** the expiration of the Orange Book patent. (*See* Dkt. 1, ¶ 34.) [redacted] Accordingly, Count 1 should be dismissed for lack of subject matter jurisdiction.

[redacted] "A case becomes moot when interim relief or events have eradicated the effects of a defendant's act or omission, and there is no reasonable expectation that the alleged violation will recur." *Ferring B.V. v. Watson Labs, Inc.*, 764 F.3d 1382, 1391 (Fed. Cir. 2014).

Indeed, [redacted] *See AstraZeneca AB*, 2014 U.S. Dist. Lexis 79201, at *17-18. In *AstraZeneca AB*, Anchen's Paragraph III conversion – made about two years after the lawsuit was filed – rendered the case moot and deprived the court of subject matter jurisdiction because Anchen was "no longer seek[ing] approval of its ANDA until after expiration of all the

applicable patents." *Id.* at *5, *17-18. AstraZeneca's argument that the possibility of Anchen converting its Paragraph III certifications back to Paragraph IV at a later date did not alter the court's conclusion. *See AstraZeneca AB*, 2014 U.S. Dist. Lexis 79201, at *14-16. The court correctly recognized that the possibility Anchen might submit a new Paragraph IV certification – a one-time act – was not analogous to the type of "repeated course of conduct" sometimes found sufficient to avoid mootness. *AstraZeneca AB*, 2014 U.S. Dist. Lexis 79201, at *16.

[redacted]

Such allegations "rest[] upon contingent future events that may not occur as anticipated, or indeed may not occur at all," and cannot form the basis for a case or controversy. *See Wyatt v. Gov't of the Virgin Islands, Inc.*, 385 F.3d 801, 806 (3d Cir. 2003) (internal citation omitted).

The *Lundbeck* court incorrectly reached the opposite conclusion on Sandoz's motion to dismiss for lack of subject matter jurisdiction. [redacted] "may only be 'hypothetical' at this point." 2020 U.S. Dist. Lexis 113213, at *9. Courts have repeatedly held that such hypothetical disputes are not justiciable and must be dismissed. *Flast v. Cohen*, 392 U.S. 83, 94 (1968) ("The judicial power of the federal courts is constitutionally restricted to 'cases' and 'controversies.'"); *Olson v. United States*, 172 F.3d

1311, 1319 (Fed. Cir. 1999) ("it is not our role to offer advisory opinions on hypothetical case or controversies"); *Astrazeneca AB*, 2014 U.S. Dist. Lexis 79201, at *14-16; *Reckitt Benckiser Pharm., Inc. v. Biodelivery Scis. Int'l, Inc.*, No. 5:13-CV-760-BO, 2014 U.S. Dist. LEXIS 69805, at *6-7 (E.D.N.C. May 20, 2014). Accordingly, the *Lundbeck* court erred in denying Sandoz's motion to dismiss on jurisdictional grounds.

The *Lundbeck* court was also swayed into an erroneous conclusion on subject matter jurisdiction based on an incorrect analysis of *Sanofi v. Lupin Atlantis Holdings SA*, No. 15-415, 2017 U.S. Dist. Lexis 10653, at *2 (D. Del. Jan. 26, 2017). In *Sanofi*, the District of Delaware had issued a judgment in 2016 enjoining Sandoz from infringing two patents listed in the Orange Book for Sanofi's Multaq®. A second case involving a third, related patent for Multaq® was also pending before the court, but on a later schedule due to the fact that the third patent was not listed in the Orange Book until the first case was near trial. *Id.* at *2-3. After unsuccessfully seeking to stay the second case pending the outcome of the appeals in the first case, Sandoz converted to Paragraph III on the third patent and sought dismissal of the second case. *Id.* at *3. In denying Sandoz's motion, the Judge Andrews was persuaded that Sandoz might submit a new Paragraph IV certification, noting that "Sandoz's pursuit of the appeal is compelling evidence of its desire to pursue launch of its generic product long before 2029." *Id.* at *8 n.3. Thus, the finding of subject matter jurisdiction in *Sanofi* was predicated on facts suggesting that Sandoz [redacted].

By contrast, [redacted] Sandoz does not have tentative approval for its ANDA and there is no co-pending litigation that suggests [redacted] Further, the '600 patent expires in less than two years. It

would make little sense [redacted] when it could not hope to receive a decision on the merits in advance of the patent's expiration. (Ex. P, U.S. District Court Judicial Caseload Profile for New Jersey (showing 40.8 months median time from filing to trial).)

b. [redacted]

In addition to a concrete injury, in order to establish standing, Merck must also demonstrate that its injury "is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).

Merck cannot meet its burden to show that any of its alleged injuries related to Count 1 are "likely to be redressed by a favorable judicial decision" because the remedies available under the Hatch-Waxman Act for Count 1 allow for no relief other than what Merck has already achieved [redacted] *See id*. As summarized in the discussion of § 271(e)(4) above, "the remedy for a prevailing plaintiff [in a Hatch-Waxman case] is an injunction delaying approval of a defendant's ANDA ***until expiration of all listed Orange Book patents***." *AstraZeneca AB*, 2014 U.S. Dist. Lexis 79201, at *16 (emphasis added). [redacted] *Id.* Merck has no redressable injury in fact, and as a result, Merck lacks standing.

C. Merck's Declaratory Judgment Count Alleging Future Infringement (Count 2) Should be Dismissed Under Fed. R. Civ. P. 12(b)(1)

Regardless of the viability of Merck's allegations of infringement of the '600 patent under §271(e)(2) (Count 1), Merck's allegations of infringement of the same patent under §§ 271(a)-(c) and the Declaratory Judgment Action (Count 2) should be dismissed for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). These allegations under the

Declaratory Judgment Act are too remote and speculative to render subject matter jurisdiction before this Court. To hold otherwise would also run counter to the framework of the Hatch-Waxman Act and Congressional intent. And, even if this Court found some controversy, it should decline to exercise declaratory judgment jurisdiction.

1. Any Alleged Controversy is Too Remote And Speculative to Support Jurisdiction

As the declaratory judgment plaintiff, Merck carries the burden to show that under the facts alleged and considering all the circumstances, there is a "substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (internal citation omitted). "Declaratory judgment jurisdiction may not be predicated on pure speculation." *In re Rosuvastatin Calcium Patent Litig.*, MDL No. 08-1949, 2008 U.S. Dist. Lexis 96289, at *48 n.12 (D. Del. Nov. 24, 2008).

Here, the purported "controversy" necessary to support a claim for declaratory judgment under §§ 271(a)-(c) has not occurred and is too remote. Merck's alleged controversy is predicated on Sandoz obtaining final FDA approval and commercially marketing its ANDA product before the expiration of the '600 patent. Specifically, Merck alleges:

> Sandoz's infringing activity, including the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's Infringing ANDA Product complained of herein, ***will begin immediately after the FDA approves Sandoz's ANDA. Any such conduct before the '600 Patent expires will directly infringe, contribute to the infringement of, or induce the infringement*** of one or more claims of the '600 Patent under one or more of 35 U.S.C. § 271(a), (b), and (c).

(Dkt. 1, ¶ 50 (emphasis added).) There is nothing real or immediate about the two highly contingent and long-distant events that would have to occur for a patent infringement claim based upon an ANDA filing to arise under §§ 271(a)-(c). [redacted]

prior to the '600 patent's expiration and an FDA grant of final approval are necessary predicates for the allegedly infringing acts described in Count 2 to occur. The future occurance of both predicate events is purely hypothetical and speculative at this time.

[redacted] As a result, as explained in greater detail in Section IV.A above, Merck cannot avail itself of § 271(e)(2) here, and as such, "cannot establish the immediacy required for a declaratory judgment action without § 271(e)(2)'s 'artificial' act of infringement." *Eisai*, 2007 U.S. Dist. Lexis 93585, at *63.

[redacted] Sandoz's proposed ANDA product has not yet been approved – even tentatively – by the FDA. Courts have frequently held that no case or controversy exists over claims for infringement under § 271(a), (b) and (c) in situations like this one where the ANDA has not received FDA approval. "[A] controversy will only materialize if the FDA approves the accused drug and if Defendant[s] decide[] to market the drug." *Abbott Labs. v. Zenith Labs., Inc.*, 934 F. Supp. 925, 939 (N.D. Ill. 1995); *see also Eisai*,

2007 U.S. Dist. Lexis 93585, at *63; *Novo Nordisk, Inc. v. Mylan Pharms., Inc.*, 2010 U.S. Dist. Lexis 32569, at *26 (D.N.J. Mar. 31, 2010) ("Because a generic-drug manufacturer has not yet placed the drug into the market when it files an ANDA application, a patent-holder cannot make a claim for patent infringement under § 271(a)"). And consequently, Count 2 does not raise a justiciable controversy that is "of sufficient immediacy and reality" to warrant a declaratory judgment. *MedImmune*, 549 U.S. at 127 (internal citation omitted). That is, "[a]t least until the ANDA is approved . . . the controversy is not sufficiently immediate." *Eisai*, 2007 U.S. Dist. Lexis 93585, at *63 (dismissing declaratory judgment claim prior to FDA approval); *see also Abbott Labs.*, 934 F. Supp. at 938-39 (same).

2. Count 2 Should be Dismissed as Contrary to The Hatch-Waxman Scheme

Additionally, Count 2 should be dismissed as inconsistent with Congressional intent in enacting the Hatch-Waxman Act, which created an artificial act of infringement: filing an ANDA. *See* 35 U.S.C. § 271(e)(2). "Congress evidently believed that a patentee in [Merck's] position did not have a cause of action under § 271(a)—indeed, the lack of such an action was a motivating factor in creating the § 271(e)(2) action." *Rosuvastatin*, 2008 U.S. Dist. Lexis 96289, at *47 (dismissing claim for declaratory judgment under Section 271(a)). That is, § 271(e)(2) "provided patentees with a defined act of infringement sufficient to *create case or controversy jurisdiction* . . . when . . . the ANDA applicant was not making, using, or selling the patented product." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) (emphasis added); *see also Eli Lilly*, 496 U.S. at 678 (noting that "the purpose of [§ 271(e)(2)] . . . is to *enable* the judicial adjudication upon which the ANDA . . . schemes depend" by creating the "highly artificial" act of patent infringement—filing an ANDA) (emphasis added); *Warner-Lambert*, 316 F.3d at 1365 (reiterating that § 271(e)(2)) "*creates case-or-controversy jurisdiction*" before the product goes to market) (emphasis added) (internal citation omitted).

But the "elaborate and specific framework" that established this "highly artificial act of infringement" of the Hatch-Waxman Act leaves no room for claims based on §§ 271(a)-(c). *See Lilly*, 496 U.S. at 678; *Rosuvastatin*, 2008 U.S. Dist. Lexis 96289, at *46. "Nothing in the Hatch-Waxman Act appears to contemplate that a patentee, at the same time it pursues the § 271(e) action created for it by the Act, would also pursue an ordinary § 271(a) patent infringement action on the same patent and based on all the same facts." *Id.* "In short, section 271(e)(2) makes it possible for the district court to exercise its section 1338(a) jurisdiction in the situation in which an ANDA has been filed." *Allergan, Inc. v. Alcon Labs., Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003); *see also Noven Therapeutics, LLC v. Actavis Labs. FL, Inc.*, No. 14-6414, 2015 U.S. Dist. Lexis 175628, at *4 (D.N.J. Feb. 20, 2015) (declining to exercise jurisdiction over duplicative declaratory judgment counts); *Abbott Labs.*, 934 F. Supp. at 938-39 (declining to exercise jurisdiction over § 271(a) claim when it would "undermine" Congress's policy in enacting Hatch-Waxman and because a controversy would materialize only after FDA approval and generic marketing); *Takeda Pharm. Co. v. Mylan Inc.*, 62 F. Supp. 3d 1115, 1127 (N.D. Cal. 2014) ("permitting Takeda to proceed on [its declaratory judgment count] appears unnecessary in light of (if not contrary to) the Hatch-Waxman Act"). Count 2, which is *not* based on § 271(e)(2), should be dismissed.

3. The Court Should Use Its Discretion to Decline to Exercise Jurisdiction if it Exists

Even if this Court finds a sufficient case or controversy exists, it should nevertheless decline to exercise declaratory judgment jurisdiction. The Court has significant discretion in determining whether or not to exercise declaratory judgment jurisdiction over Merck's "possible" infringement claims. *See Matthews Int'l Corp. v. Biosafe Eng'g, LLC*, 695 F.3d 1322, 1328 n.3 (Fed. Cir. 2012).

Here, as described above, the declaratory judgment claims based on ordinary infringement are inconsistent with the Hatch-Waxman Act. *See Rosuvastatin*, 2008 U.S. Dist. Lexis 96289, at *47; *Takeda Pharm.*, 62 F. Supp. 3d at 1127. Should it conclude that jurisdiction exists, the Court should nevertheless decline to exercise it. *See Abbott Labs.*, 934 F. Supp. at 938-39 (declining to exercise jurisdiction over § 271(a) claim when it would "undermine" Congress's policy in enacting Hatch-Waxman and because a controversy would materialize only after FDA approval and generic marketing); *Noven*, 2015 U.S. Dist. Lexis 175628, at *4 (same).

V. CONCLUSION

For the foregoing reasons, Sandoz respectfully requests that this Court dismiss Count 1 pursuant to Fed. R. Civ. P. 12(b)(6) and 12(b)(1), and dismiss Count 2 of Merck's complaint under Fed. R. Civ. P. 12(b)(1).

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